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Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 10/019,643

Confirmation No.: 1109

Filed: March 20, 2002

For: METHOD AND COMPOSITION FOR AFFECTING REPRODUCTIVE SYSTEMS**Remarks**

The Final Office Action mailed September 22, 2004, has been received and reviewed. The pending claims are claims 4, 6, 12-21, 23, and 27-29. Reconsideration and withdrawal of the rejections are respectfully requested. The Examiner is kindly requested to consider the following additional remarks in response to the claim rejections, and also to enter on the record the Supplemental Information Disclosure Statement submitted herewith, which lists one document, "Drug Information: Medroxyprogesterone," American Society of Health Systems Pharmacists, Inc., which is cited by the Applicant in the remarks below. It is respectfully submitted that consideration of these remarks will place the application in condition for allowance.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 4, 6, 12-21, 23, and 27-29 under 35 U.S.C. §112, first paragraph, alleging the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants respectfully traverse this rejection.

Specifically, the Examiner asserted that the specification, while being enabling for treating a reproductive disease that is related to egg laying or fertilization, does not reasonably provide enablement for treating cystic hyperplasia. Applicants respectfully disagree.

In the previous office action mailed May 5, 2004, the Examiner asserted:

Applicant's invention is drawn to administering a zona pellucida protein to help treat fertility and reproductive [disorders] associated with egg laying in birds. The administration of said zona pellucida proteins, elicits antibodies against the zona pellucida present on ova in the hens. When the antibodies bind to the zona pellucida proteins they sterically hinder the ability of the sperm from male chickens to fertilize the hen ova. It is reasonable to control fertility in these hens with such a treatment . . . [I]t has not been recognized by science that preventing fertility would help treat . . . cystic hyperplasia.

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Applicants respectfully submit that the Examiner's description of the effects of immunization with zona pellucida proteins is incomplete and, as a consequence, too narrow. Antibodies against zona pellucida proteins impact not only fertilization, by interfering with the interaction of sperm with egg, but also more broadly impact fertility by influencing ovarian structure and function (U.S. Patent No. 5,736,141 (see col. 1, lines 42-49) (*cited on 1449 form mailed 02/11/03*); Barber and Fayrer-Hosken, (2000) J. Reprod. Immunol. 26:103-124 (see p. 112) (*cited on 1449 form mailed 02/11/03*); and WO 99/34825 (see p. 6, line 3 to p. 7, line 5, p. 7, lines 21-24, and p. 13, lines 13-20) (*cited on 1449 form mailed 02/11/03*)). For example, the immunization of mares with porcine zona pellucida results in decreased levels of estrogen and in the disruption of ovulation (Willis et al., (1994) J. Equine Veterinary Science 14(7):364-370, (see p. 365) and Kirkpatrick et al., (1992) J. Reprod. Fert. 94:437-444 (see abstract and p. 442) (*cited on 1449 form mailed 02/11/03*)). And, the effect of immunization with zona pellucida proteins on avian ovaries is shown in the present specification (see p. 9, lines 1-4, p. 17, line 21 to p. 18, line 4 and p. 23, lines 25-29).

The Examiner asserted that Applicants have failed to provide a nexus between cystic hyperplasia and fertilization. However, Applicants submit that a more appropriate question, in view of the above discussion, is whether there is a nexus between cystic hyperplasia and fertility. Applicants respectfully submit that there is indeed a well-established and art-recognized nexus between cystic hyperplasia and fertility.

The Examiner himself cited teachings found in the Merck Manual for Diagnosis and Therapy, that "cystic hyperplasia, a possible cause of dysfunctional uterine bleeding, is treated inhibiting the menstrual cycle with medroxyprogesterone" (page 2, Office Action mailed September 22, 2004). Inhibition of the menstrual cycle clearly affects fertility, thus these teachings support a nexus between cystic hyperplasia and fertility. Indeed, medroxyprogesterone is also administered as a contraceptive to prevent ovulation and pregnancy (see Drug Information: Medroxyprogesterone, a copy of which is provided with the Information Disclosure Statement, filed herewith). Moreover, the instant specification describes administration of medroxyprogesterone to temporarily stop ovulation (see page 1, lines 31-32,

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and page 2, lines 24-25 of the specification). Administration of a compound such as zona pellucida protein that disrupts ovulation or otherwise influences the menstrual cycle would very reasonably be expected to successfully treat cystic hyperplasia.

Applicants submit that the pending claims are thus fully enabled. Reconsideration and withdrawal of the rejection of claims 4, 6, 12-21, 23, and 27-29 under 35 U.S.C. §1.112, first paragraph, is respectfully requested.

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It is respectfully submitted that the pending claims 4, 6, 12-21, 23, and 27-29 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 16 day of DECEMBER, 2004, at 10:00 A.M. (Central Time).

By: Sandy Truehart
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